MAY 2 8 2014

510(k) Summary
(As Required by 21 CFR 807.92)

22 May 2014

This 510(k) Summary of safety and effectiveness for the Clinical Innovations ClearView Total is submitted with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(k) summary.

Submitter Information

Company Name:	Clinical Innovations
Company Address:	747 West 4170 South Murray, UT 84123
Company Phone:	801-268-8200
Company Fax:	801-266-7373

Device Identification

Device trade name:	ClearView Total
Device Common Name:	Cannula, Manipulator/Injector, Uterine
Classification:	Unclassified per Pre-Amendment
Product Code:	LKF
Device Class:	Unclassified
Establishment Registration Number:	1722684

Contact Person
Tom Haueter
Director, Quality Assurance and Regulatory Affairs
801-260-6028
T.Haueter@clinicalinnovations.com

Predicate Devices:

Clinical Innovations ClearView® (K940681)

ConMed VCARE (K071907)

The Koh Colpotomizer™ System (K954311)

Device Description:

Clinical Innovations' ClearView Total is a single-use sterile device used for uterine manipulation. Uterine manipulation is essential for laparoscopies involving the female pelvic organs (uterus, tubes, ovaries) when a uterus is present. Uterine manipulators may be helpful when clinicians perform tubal ligations, diagnostic laparoscopies for evaluating pelvic pain and infertility, treatment of endometriosis, removal of pelvic scars (adhesions) involving the uterus, fallopian tubes and ovaries, treatment of ectopic pregnancy, removal of uterine fibroids, removal of ovarian cysts, removal of ovaries, tubal repair, laparoscopic hysterectomy, laparoscopic repair of pelvic bowel or bladder, sampling of pelvic lymph nodes, laparoscopic bladder suspension procedures for treatment of incontinence, and biopsy of pelvic masses.

The ColpoCup accessory is a plastic cup which is mechanically screwed into the tip of the uterine manipulator. The ColpoCup is compatible with typical surgical devices, including harmonics and electrosurgical tools. Three different sizes of ColpoCups will be included with the device; 3.0cm, 3.5cm, and 4.0cm. Each ColpoCup will be a high contrast color in order to provide the surgeon with clear visibility during laparoscopic dissection.

At the base of the ColpoCup, past the tip pivot point, is a pre-attached Occluder constructed of an inflatable balloon and will be included to seal off the vagina and prevent pnuemoperitoneum loss. The Occluder Balloon is connected to a separate inflation valve which is located proximally from the balloon and allows for inflation after placement.

Indications for Use:

The ClearView Uterine Manipulator Device with ColpoCup and Occluder is intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.

Indications for Use Comparison:

Property	Result
Laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision	Similar to predicate device, The Koh Colpotomizer™ System Similar to predicate device, Clinical Innovations® ClearView
Laparoscopically assisted vaginal hysterectomies,	Similar to predicate device, the ConMed VCARE Similar to predicate device, Clinical Innovations® ClearView
Total laparoscopic hysterectomies	Similar to predicate device, the ConMed VCARE

Technical Characteristics Comparison:

Property	Result
Sterile, Single-use	Similar to predicate device, ConMed VCARE Similar to predicate device, Clinical Innovations® ClearView
Distal holes that allow suture fixation if desired	Similar to predicate device, ConMed VCARE
Three different cup sizes; 3.5cm, 4.0cm, 4.5cm	Similar to predicate device, The Koh Colpotomizer™ System
Distal handle for uterus manipulation	Similar to predicate device, The Koh Colpotomizer™ System Similar to predicate device, Clinical Innovations® ClearView
Occluding balloon to maintain proper peumoperitoneum pressure during surgery.	Similar to predicate device, The Koh Colpotomizer™ System
Inflatable (saline-filled) balloon for insertion into uterus	Similar to predicate device, ConMed VCARE Similar to predicate device, Clinical Innovations® ClearView

Summary of Studies

Clinical Innovations performed device integrity testing to support the claim that the device is substantially equivalent to the predicate devices. All device integrity tests for the ClearView Total met the specified requirements, which consisted of:

- Accelerated Age Testing
- Balloon Leak/Burst Testing
- Cup Security and Cup Break

Clinical Innovations conducted the following biocompatibility testing in accordance to relevant industry standards:

- Cytotoxicity
- Intracutaneous Reactivity Irritation
- Sensitization

All testing met the appropriate acceptance criteria.

Basis for Substantial Equivalence:

Clinical Innovations believes that the ClearView Total is substantially equivalent based on the similarities to the predicate devices in indications and technical properties. Further, the ClearView Total introduces no new intentions, indications, or technical properties than exist currently in the previously cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

Clinical Innovations, LLC
Tom Haueter
Director, Quality and Regulatory Affairs
747 West 4170 South
Murray, UT 84123

Re: K131781
Trade/Device Name: ClearView Total
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: May 1, 2014
Received: May 2, 2014

Dear Tom Haueter,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131781

Device Name: ClearView Total

Indications for Use:

The ClearView Total is intended for use in laparoscopic procedures where it is desirable to delineate the vaginal fornices and the surgeon intends to remove or access intraperitonial tissue through the vagina by use of a colpotomy or culdotomy incision; such as laparoscopically assisted vaginal hysterectomies, total laparoscopic hysterectomies, while maintaining pneumoperitoneum by sealing the vagina while a colpotomy is performed.

Prescription Use__X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2014.05.28 13:13:53 -04'00'